Exhibit Q

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION This document relates to: *All Actions*	MDL No. 19-2875 (RBK/KW)

SPECIAL MASTER ORDER NO. __

THIS MATTER having been brought before the Court by way of the Motion to Seal Pursuant to Local Civil Rule 5.3 (the "Motion to Seal") filed by Defendants Zhejiang Huahai Pharmaceutical Co., Ltd., Prinston Pharmaceutical Inc., Huahai U.S. Inc., and Solco Healthcare US, LLC (collectively, "the ZHP Parties" or "ZHP") on notice to liaison counsel for Plaintiffs; and the Court having considered the Parties' submissions and proposed sealed information, and the factors contained in Local Civil Rule 5.3(c)(2); and the Court having further found that the standards set forth therein have not been met, the Court makes the following Findings of Fact and Conclusions of Law:

1. Preliminarily, the Court notes that "in cases involving large-scale discovery, the court may construct a broad umbrella protective order upon a threshold showing by the movant of good cause." *In re Avandia Mktg., Sales, and*

Prods. Liab. Litig., 924 F.3d 662, 671 n.5 (3d Cir. 2019) (quoting *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 787 n.17 (3d Cir. 1994)). "However, Courts must be vigilant to assure Confidentiality Orders are not overused and are only used for legitimate purposes." *In re Valsartan N-Nitrosodimethylamine (NDMA), Losartan, and Irbesartan Prods. Liab. Litig.*, --- F. Supp. 3d ----, 2021 WL 75258, at *2 (D.N.J. Jan. 8, 2021). This Court has previously noted that "the purpose of entering a protective order is not to insulate a party from the annoyance, embarrassment, oppression, or burden that may be caused by having to defend claims of wrongdoing the details of which appear in materials produced during discovery." *Id.* (emphasis added) (citing *American Financial Svcs., Inc. v. Reserve Fund, C.A.*, No. 08-5219 (PAM/JJK), 2008 WL 11456114, at *3 (D. Minn. Dec. 15, 2008)).

2. Thus, when a party challenges a designation under an umbrella protective order, "'the party seeking to maintain the seal must justify the continued sealing of those documents..." *Avandia*, 23 F. 3d at 671 n.5 (quoting *Pansy*, 23 F.3d at 787 n.17). "In *Pansy v. Stroudsburg*, 23 F. 3d 772 (3rd Cir. 1994), the court expounded on the burden to justify confidentiality." *Valsartan*, 2021 WL 75258, at *3. There, the Third Circuit set forth seven factors to consider when deciding a motion to seal:

1. whether disclosure will violate any privacy interests;
2. whether the information is being sought for a legitimate purpose or for an improper purpose;

> 3. whether disclosure of the information will cause a party embarrassment;[1]
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> 4. whether confidentiality is being sought over information important to public health and safety;
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> 5. whether the sharing of information among litigants will promote fairness and efficiency;
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> 6. whether a party benefitting from the order of confidentiality is a public entity or official; and
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> 7. whether the case involves issues important to the public.

Avandia, 924 F.3d at 671 (emphasis added) (quoting *Glenmede Tr. Co. v. Thompson*, 56 F.3 476, 483 (3d Cir. 1995) (citing *Pansy*, 23 F.3d at 787-91)). In *Pansy*, the Third Circuit also held that "where it is likely that information is accessible under a relevant freedom of information law, a strong presumption exists against granting or maintaining an order of confidentiality whose scope would prevent disclosure of that information pursuant to the relevant freedom of information law." 23 F.3d at 791. Importantly, this standard applies "when [a court] review[s] orders preserving the

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[1] "Although 'preventing embarrassment may be a factor satisfying the "good cause" standard,' the proponent of a protective order 'must demonstrate that the embarrassment will be particularly serious.'" *Avandia*, 23 F.3d at 671 n.6 (quoting *Pansy*, 23 F.3d at 787). "As embarrassment is usually thought of as a nonmonetizable harm to individuals, it may be especially difficult for a business enterprise, whose primary measure of well-being is presumably monetizable, to argue for a protective order on this ground." *Pansy*, 23 F.3d at 787 (emphasis added) (quoting *Cipollone v. Liggett Group, Inc.*, 785 F.2d 1108, 1121 (3d Cir. 1986), *cert. denied*, 484 U.S. 976 (1987)).

confidentiality of discovery materials pursuant to Federal Rule of Civil Procedure 26." *Avandia*, 924 F.3d at 670 (citing *Pansy*, 26 F.3d at 783-92).

3. "[T]he more rigorous common law right of access [applies] when discovery materials are filed as court documents. In addition to recognizing fewer reasons to justify the sealing of court records, the public right of access—unlike a Rule 26 inquiry—begins with a presumption in favor of public access." *Id.* (emphasis added) (citing *Goldstein v. Forbes (In re Cendant Corp.)*, 260 F.3d 183, 192–93 (3d Cir. 2001)).[2]

> The common law right of access "antedates the Constitution." *Bank of Am. Nat'l Tr. & Sav. Ass'n v. Hotel Rittenhouse Assocs.*, 800 F.2d [339,] 343 [(3d Cir. 1986)]. The right of access "promotes public confidence in the judicial system by enhancing testimonial trustworthiness and the quality of justice dispensed by the court." *Littlejohn v. BIC Corp.*, 851 F.2d 673, 678 (3d Cir. 1988). Public observation facilitated by the right of access "diminishes possibilities for injustice, incompetence, perjury, and fraud." *Id.* Moreover, "the very openness of the process should provide the public with a more complete understanding of the judicial system and a better perception of its fairness." *Id.*

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[2] ZHP's proposed order cites *Rutigliano v. Appleton Papers, Inc.*, No. 90-1432, 2000 WL 1705152 at *5 (D.N.J. Oct. 6, 2000), for the proposition that "[t]he scale is tipped in favor of confidentiality where the parties relied on a prior confidentiality order." (Defs.' Proposed Order ¶ 14, ECF 859-4). That unpublished district court case involved a pro se plaintiff's attempt to overturn an umbrella protective order, not a motion to seal judicial records. *Rutigliano*, 2000 WL 1705152 at *3. It is completely inapposite to ZHP's motion and does not stand for the proposition for which ZHP cited it. To the extent it did, *Avandia* would clearly control.

Avandia, 924 F.3d at 672. Thus, once a document "has been filed with the court . . . or otherwise somehow incorporated or integrated into a district court's adjudicatory proceedings," "a presumption of access attaches."[3] *Id.* (emphasis added) (quoting *In re Cendant Corp.*, 260 F.3d at 192).

4. "To overcome that strong presumption, the District Court must articulate 'the compelling, countervailing interests to be protected,' make 'specific findings on the record concerning the effects of disclosure,' and 'provide[ ] an opportunity for interested third parties to be heard.'" *Id.* at 672-73 (quoting *In re Cendant Corp.*, 260 F.3d at 194). "In delineating the injury to be prevented, specificity is essential," so "[b]road allegations of harm, bereft of specific examples or articulated reasoning, are insufficient." *Id.* at 673 (quoting *In re Cendant Corp.*, 260 F.3d at 194) (emphasis added). In sum, "[c]areful factfinding and balancing of competing interests is required before the strong presumption of openness can be overcome by the secrecy interests of private litigants." *Id.* (emphasis added) (quoting *Leucadia, Inc. v. Applied Extrusion Techs., Inc.*, 998 F.2d 157, 167 (3d Cir. 1993)).

[3] Torrent's records were not filed with the Court, so this Court did not discuss the common law right of access in *Valsartan*, 2021 WL 75258. ZHP's motion concerns records that were all filed with the Court. In either case the documents at issue cannot legitimately be maintained as confidential.

5. Moreover, although some of the seven *Pansy* factors are relevant to a court's analysis under the common law standard, two are explicitly not considered. *Id.* at 677. First, the Third Circuit has "repeatedly said that concern about a company's public image, embarrassment, or reputational injury, without more, is insufficient to rebut the presumption of public access." *Id.* (emphasis added) (collecting cases). Second, "a person's motive for inspecting or copying judicial records is irrelevant under the common law right of access." *Id.* at 677.

6. In considering the remaining five factors, the Third Circuit has put its "thumb on the scale in favor of openness—the strong presumption of public access[:]"

> [T]he public's right of access must be the starting point, not just one of multiple factors. The scale is tipped at the outset in favor of access. And the right of access is not a mere formality—it "promotes public confidence in the judicial system"; "diminishes possibilities for injustice, incompetence, perjury, and fraud"; and "provide[s] the public with a more complete understanding of the judicial system and a better perception of its fairness." *Littlejohn*, 851 F.2d at 678. These interests are particularly important in a case such as this one, which implicates the public's trust in a well-known and (formerly) widely-used drug.

Avandia, 924 F. 3d at 677 (emphasis added). Moreover, "[s]ealing must be based on *current evidence* to show how public dissemination of the pertinent materials *now* would cause the competitive harm." *Id.* at 678 (quoting *In re Cendant Corp.*, 260 F.3d at 196). On the other hand, "blanket assertions of harm that 'could' come to

fruition fall short of the clearly defined and serious injury that [a movant] must articulate to obtain sealing under any standard." *Id.* at 679. As discussed below, ZHP fails that test, and cannot meet it with regard to presumptively public documentation of the facts surrounding its wholesale contamination of a trusted blood pressure drug, a drug that is no longer sold by ZHP in the United States.

7. After the Third Circuit vacated and remanded its original decision to seal the documents in *Avandia*, the trial court applied the correct standard and wrote:

> Justice Brandeis famously declared that "sunlight is the most powerful of all disinfectants." Considering the common law presumption of public access, the lack of harm GSK will face, the significance of this litigation, and the number of people affected, light must shine on these documents. Therefore, for the reasons stated above, GSK's Motion for the Continued Sealing of Certain Documents will be granted only as to the redaction of personal information of study subjects and employee telephone numbers, addresses, and the ending of email addresses and otherwise denied, and GSK's Motion for the Continued Sealing of the Expert Reports of Donald Austin, Eliot Brinton, and Brian Swirsky will be denied.
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> *In re Avandia Mktg, Sales Practices and Prods. Liab. Litig.*, --- F. Supp. 3d ----, 2020 WL 5358287, at *12 (E.D. Pa. Sept. 3, 2020) (emphasis added) (footnote and citations omitted).

8. This Court has already applied the *Pansy* factors to unfiled discovery materials. The Court noted that it "is not required to give credence to [a] conclusory self-serving affidavit that is inconsistent with the Court's independent review of [the] documents." *Valsartan*, 2021 WL 75258, at *5. Instead, the Court found that "[a]t

bottom, Torrent's emails involve what appears to be routine business communications." *Id*. at *6. The Court also rejected the argument that the authors or recipients expected the documents to remain confidential, explaining "[o]therwise, large swatches of routine emails would be kept under wraps." *Id.* Given this substantive ruling that Torrent had over designated its documents, the Court further ordered that "Torrent shall apply the Court's ruling as to its exemplar documents to all of its Confidentiality designations. To the extent similar documents are designated Confidential, the designations shall be removed," and "Torrent shall notify plaintiffs which of its Confidentiality designations . . . are removed." *Id.* at *8. This Court also noted that a defendant waives its confidentiality designations when it fails to file a motion to seal within the appropriate time period. *Id.* at *4 n.5.[4]

9. In this motion, ZHP has asked the Court to seal twenty-nine documents. All of these documents were filed with the Court, with the exception of one, which was cited and discussed in a court filing. In accordance with Third Circuit precedent,

[4] In fact, ZHP did not move to seal the documents to which these twenty-nine exhibits were attached, one of which was significantly redacted (ECF 685), nor did it move to seal the documents that Plaintiffs challenged in their November 18, 2020 letter. (Pls.' Ex. P). As a result of not moving to seal these documents, they are no longer confidential. Plaintiffs attached ECF 685 and the documents challenged in their November 18, 2020 letter as Exhibits A-H of their brief so that the Court could see how similar they are to the documents at issue in this motion. Plaintiffs also attached the documents subject to the Court's earlier decision as Exhibits I-M of their brief.

ZHP's proposed order concedes that the common law public right of access applies to all these documents. (ECF 859-4 ¶ 10). *See also Avandia*, 924 F.3d at 672.

10. In addition to "the strong presumption" against sealing these judicial records, this Court recognizes the significant public interest in understanding the nitrosamine contamination at issue in this case. *Avandia*, 924 F. 3d 677. ZHP was the first pharmaceutical manufacturer to recall its drugs due to their contamination with carcinogenic nitrosamines, and the issue is not limited to valsartan, losartan, and irbesartan. FDA, *Recalls of Angiotensin II Receptor Blockers (ARBs) including Valsartan, Losartan and Irbesartan*, https://tinyurl.com/1k9w9jid; FDA, *Information about Nitrosamine Impurities in Medications*, https://tinyurl.com/1tu3nih0. There is an ongoing public investigation into the cause of this widespread contamination, whether it has occurred with other drugs, and how to prevent it in the future, on top of the FDA's firm determination that the contamination was wrongful and unacceptable, resulting in a complete recall and import ban against ZHP. (Pls.' Ex. F). In fact, ZHP is still banned from importing its valsartan into the United States because it has not addressed its contamination to the satisfaction of the FDA. FDA, Import Alert 66-40, https://tinyurl.com/3jxjmcxc.

11. There is simply no reasonable argument for shielding documentation of this disaster from the public. It is preposterous to argue that ZHP can, let alone should, be able to monopolize the information needed for a true understanding of the

nitrosamine contamination of its valsartan. As explained in greater detail below, this Court therefore denies ZHP's motion to seal each of the twenty-nine documents:

1. ZHP00305868 (ECF 638, Ex. 4): A January 31, 2018 supplier report that discusses cGMP violations related to ZHP's manufacture of valsartan. Preliminarily, neither party to this document should be concerned about its release, as it shows ZHP's responses to a customer's valid concerns. ZHP argues that failing to seal this document would cause it embarrassment. However, embarrassment is not a basis for sealing judicial records. *Avandia*, 924 F.3d at 677. ZHP also claims that the record is not relevant to this litigation, but that is clearly false as ZHP would not have produced it to Plaintiffs if it were irrelevant. More specifically, ZHP's cGMP violations in cleaning and maintaining their equipment likely resulted in cross contamination between their different valsartan manufacturing processes, as discussed in ZHP's own deviation investigation reports. This document is also very similar to Plaintiffs' Exhibits B, C, D, and F, which ZHP no longer maintains are confidential, as well as Plaintiffs' Exhibits I, K, and M, which this Court has already ruled are not confidential. *Valsartan*, 2021 WL 75258, at *8. ZHP also relies on the document's reference to confidentiality, but this Court has already rejected a party's own designation of a document as confidential as a basis for sealing a document in this litigation. *Id.* at *6 (stating "[o]therwise, large swatches of routine emails would

be kept under wraps"). The public's right to access this document thus outweighs any interest in keeping it under seal.

2. ZHP00385769 (ECF 638, Ex. 5): An August 27, 2018 deviation investigation report attempting to explain the root cause of the nitrosamine contamination of ZHP's valsartan. This information is very similar to the information that Torrent unsuccessfully sought to hide, and has been discussed publicly and in documents that ZHP no longer maintains are confidential. (Pls.' Exs. B-C, D, F, I, K, M). Although the report discusses the details of ZHP's manufacturing processes, those processes all contaminated its valsartan with carcinogenic nitrosamines. There is no competitive proprietary basis to shield such information. As explained above, the public has a right to know how ZHP's valsartan became contaminated with nitrosamines and how a similar disaster can be avoided in the future. That public right to access this document greatly outweighs ZHP's interest in keeping shielded from the sun's disinfecting rays. *See Avandia*, 924 F. 3d at 677; *Avandia*, 2020 WL 5358287, at *12.

3. ZHP00479762 (ECF 638, Ex. 7): Customer communications regarding the detection of unknown impurities during residual solvent testing of ZHP's valsartan – which by definition are not entitled to be deemed confidential since they involve outside entities. ZHP's potential customer Novartis discovered ZHP's nitrosamine contamination during its routine residual solvent testing. This email string does not

discuss such testing in any detail, and even if it did, there is nothing that justifies hiding the fact that ZHP's testing failed to reveal the nitrosamine contamination. It is also similar to documents that are no longer confidential in this litigation. (Pls.' Exs. B, C, D, F, I, K, M). As already explained, the public's right to fully understand and ultimately prevent this type of contamination greatly outweighs ZHP's interest in concealing its deficient residual solvent testing. *See Avandia*, 924 F. 3d at 677.

4. ZHP00493010 (ECF, 638, Ex. 8): Customer communications regarding ZHP's failure to identify unknown peaks in residual solvent testing. This email string does not discuss residual solvent testing in great detail, and even if it did, that testing is routine. As with the other examples, ZHP is simply seeking to hide its deficiencies from the public. In fact, ZHP's own subsidiary, Shanghai Syncores told it that "[t]he synthesis process of crude valsartan and the purification process including the solvent system need to be further optimized at the pilot scale." (PRINSTONO0156805, Pls.' Ex. D). However, ZHP ignored this advice and immediately used this new manufacturing process at a commercial scale "without conducting a formal risk assessment to evaluate the potential impact of changes . . . on the quality of intermediates and APIs." (PRINSTONO0073432, Pls.' Ex. B). Thus, the public's right to fully understand and ultimately prevent this type of contamination greatly outweighs ZHP's interest in concealing its defective residual solvent testing. *See Avandia*, 924 F. 3d at 677.

5. ZHP00423144 (ECF 638, Ex. 6): Customer communications regarding ZHP's monitoring of its valsartan for genotoxic impurities. This email chain does not contain any substantive information that a competitor could adopt to its competitive advantage, and nor does ZHP make any compelling argument on this front. It simply confirms that ZHP did not monitor its valsartan for genotoxic impurities, as explained in other now public documents. (Pls.' Exs. B, C, D, F, I, K, M). The public's right to fully understand and ultimately prevent this type of contamination greatly outweighs ZHP's interest in concealing that it declined to monitor its valsartan for such a contamination. *Avandia*, 924 F. 3d at 677.

6. PRINBURY00129588 (ECF 685, Ex. B): A draft response to post-recall inspection observations by the United States Food & Drug Administration ("FDA"), explaining the ZHP Parties' sampling and testing procedures, internal impact assessments, and corrective and protective actions taken in response to the FDA's observations. Once again, all of this information concerns processes that contributed to the contamination of ZHP's valsartan with carcinogenic nitrosamines, much of which is already publicly available. (Pls.' Exs. B-C, D, F, I, K, M). None of ZHP's competitors are going to adopt these failed processes, and the public – and ZHP's competitors – have a right to access these documents in order to learn how the contamination occurred and how it can be prevented in the future. That is at the heart of why this information should be public. *Avandia*, 924 F. 3d at 677.

7. ZHP00076700 (ECF 685, Ex. C): Communications between the ZHP Parties and their tax preparer for purposes of obtaining tax advice. Obviously, this email is not subject to the attorney-client privilege, as ZHP produced it to Plaintiffs. There is no independent "tax preparer" privilege, and the Court will not create one in order to shield this email chain from disclosure. Moreover, the email chain contains very little financial information, and without additional context, it is impossible to draw any significant concrete conclusions regarding ZHP's finances or taxes. Instead, Plaintiffs attached this email to their December 21, 2020 letter because it showed that ZHP Executive Vice President Jun Du received a detailed ZHP organization chart in English weeks before he met with Plaintiffs and Judge Schneider, where ZHP only produced Chinese organizations charts that failed to show ZHP General Manager Baohua Chen's central involvement in ZHP, Shanghai Syncores, and ZHP's other subsidiaries. ZHP has not given the Court any valid reason to override the public's right to access this routine business document. *Avandia*, 924 F. 3d at 677; *Valsartan*, 2021 WL 75258, at *6 (reviewing Plaintiffs' Exhibits I, J, L, and M, and finding that "[a]t bottom, Torrent's emails involve what appears to be routine business communications" and therefore not confidential).

8. PRINSTON00083640 (ECF 685, Ex. E): An FDA pre-approval establishment inspection report for the period of June 24, 2019, through June 28, 2019, that describes the ZHP Parties' manufacturing operations pertaining to various

drug products, including valsartan and its recall. This is an FDA document redacted in accordance with the Freedom of Information Act and is therefore accessible in this form in accordance with that Act. ZHP's reflexive designation of all documents as confidential, even those already publicly available, speaks volumes to the unfortunate lack of credibility to their position. The Court denies ZHP's request to seal such a document, especially in light of the public's right to access it as a judicial record concerning the contamination and recall of ZHP's nitrosamine-laced valsartan. *See Avandia*, 924 F. 3d at 677; *Pansy*, 23 F.3d at 791. ZHP seems to have recognized the weakness of its position when it declined to request the sealing of Plaintiff's Exhibits C, E, F, and G.

9. PRINSTON00077836 (ECF 685, Ex. F): A September 20, 2007 module providing a summary of the TIN manufacturing process for valsartan. ZHP no longer uses this manufacturing process, which did not cause nitrosamine contamination, because it was deemed too expensive. ZHP cannot credibly claim competitive harm from disclosing information about this abandoned manufacturing process, especially since ZHP has already shared this information with its customers, regulators, and others. *See Avandia*, 924 F. 3d at 678. Moreover, the public has the right to understand this manufacturing process in order to contextualize ZHP's subsequent manufacturing processes, all of which contaminated their valsartan with

nitrosamines. The Court therefore denies ZHP's motion to seal this document. *See Avandia*, 924 F. 3d at 677.

10. PRINSTON00082994 (ECF 685, Ex. H): An August 2013 FDA establishment inspection report of the site that manufactured ZHP's finished dose valsartan. The FDA redacted this document in accordance with the Freedom of Information Act and is therefore accessible in this form in accordance with that Act. The Court denies ZHP's request to seal this already public regulatory document, especially in light of the public's right to access it as a judicial record concerning the facility that manufactured ZHP's contaminated valsartan finished dose. Moreover, the large amount of detailed information in this public document demonstrates that the same and similar information found in the internal ZHP documents cited cannot reasonably be protected as confidential – as that and more is already public. *See Avandia*, 924 F. 3d at 677; *Pansy*, 23 F.3d at 791.

11. ZHP00107709 ECF 685, Ex. I): A May 2014 FDA establishment inspection report describing the ZHP Parties' manufacturing operations pertaining to various drug products, including valsartan. The FDA redacted this document in accordance with the Freedom of Information Act and is therefore accessible in this form in accordance with that Act. The Court denies ZHP's request to seal this already public document, especially in light of the public's right to access it as a

judicial record concerning the facility that manufactured ZHP's contaminated valsartan finished dose. *See Avandia*, 924 F. 3d at 677; *Pansy*, 23 F.3d at 791.

12. PRINSTON0074125 (ECF 685, Ex. J): This is the same document as, item #11, (ZHP00107709 ECF 685, Pls.' Ex. I), albeit with a different bates number. The Court denies ZHP's motion to seal this document for the same reason as explained in the previous paragraph.

13. PRINSTON00083026 (ECF 685, Ex. K): A March 2015 FDA establishment inspection report describing the ZHP Parties' manufacturing operations at the site that manufactured its contaminated valsartan finished dose. The FDA redacted this document in accordance with the Freedom of Information Act and is therefore accessible in this form in accordance with that act. The Court denies ZHP's request to seal such a document, especially in light of the public's right to access it as a judicial record concerning the facility that manufactured ZHP's contaminated valsartan finished dose. *See Avandia*, 924 F. 3d at 677; *Pansy*, 23 F.3d at 791.

14. PRINSTON00081549 (ECF 685, Ex. L): A November 2016 FDA inspection report describing the ZHP Parties' manufacturing operations at the site that manufactured its contaminated valsartan finished dose. The FDA redacted this document in accordance with the Freedom of Information Act and is therefore accessible in this form in accordance with that act. The Court denies ZHP's request

to seal such a document, especially in light of the public's right to access it as a judicial record concerning the facility that manufactured ZHP's contaminated valsartan finished dose. *See Avandia*, 924 F. 3d at 677; *Pansy*, 23 F.3d at 791.

15. PRINSTON00081570 ECF 685, Ex. N): A January 2018 FDA inspection report describing the ZHP Parties' manufacturing operations at the site that manufactured its contaminated valsartan finished dose. The FDA redacted this document in accordance with the Freedom of Information Act and is therefore accessible in this form in accordance with that act. The Court denies ZHP's request to seal such a document, especially in light of the public's right to access it as a judicial record concerning the facility that manufactured ZHP's contaminated valsartan finished dose. *See Avandia*, 924 F. 3d at 677; *Pansy*, 23 F.3d at 791.

16. ZHP0000215 (ECF 685, Ex. P): A 2010 business agreement between ZHP and another related company, Shanghai Syncores, for Shanghai Syncores to develop the manufacturing process that led to the nitrosamine contamination of ZHP'S valsartan. This email string does not discuss the desired manufacturing process in great detail, and even if it did, that manufacturing process contaminated its valsartan with carcinogenic nitrosamines, and is the subject of public discussion and documents, including Shanghai Syncores' report on this process. (Pls.' Ex. D). Thus, the public's right to fully understand and ultimately prevent this type of

contamination greatly outweighs ZHP's interest in concealing its defective valsartan manufacturing process. *See Avandia*, 924 F. 3d at 677.

17. ZHP02579748 (ECF 685, Ex. Q): November 2013 meeting notes disclosing valsartan API process optimization strategies. Nearly eight years old, these notes can hardly afford anyone a competitive advantage over ZHP, and in this industry this information is routine. *See Avandia*, 924 F. 3d at 678. Moreover, they discuss the background behind ZHP's development of its new valsartan manufacturing processes, which is important in order to understand the root cause of the contamination. As already mentioned, many other public documents discuss this issue in greater detail. (Pls.' Exs. B-C, D, F, I, K, M). The public's right to access these notes therefore outweighs ZHP's interest in shielding them from the sun's disinfecting rays. *See Avandia*, 924 F. 3d at 677; *Avandia*, 2020 WL 5358287, at *12.

18. ZHP00494048 (ECF 685, Ex. S): ZHP's protocol governing the recall of foreign-grade valsartan API that provides information about the ZHP parties' recall of Valsartan. This Court has already ruled that documents concerning Defendants' recall of valsartan are not confidential, even under the more liberal standard for documents not filed with the Court. *Valsartan*, 2021 WL 75258, at *6 (finding that "although Torrent argues its customers may gain insight into how it handled its recall and investigation, there is no support to show that Torrent did anything different than

any other similarly situated company"). (*See also* Pls.' Exs. I-M). Moreover, the public's right to access these documents and fully understand ZHP's recall of its contaminated valsartan would greatly outweigh ZHP's interest in concealing its recall practices. *See Avandia*, 924 F. 3d at 677.

19. PRINSTON00162373 (ECF 685, Ex. R): A July 2018 FDA establishment inspection report documenting the FDA's inspection of the ZHP Parties' manufacturing facility that manufactured its nitrosamine contaminated valsartan API. The FDA redacted this document in accordance with the Freedom of Information Act and is therefore accessible in this form in accordance with that act. The Court denies ZHP's request to seal such a document, especially in light of the public's right to access it as a judicial record concerning the facility that manufactured ZHP's contaminated valsartan API. *See Avandia*, 924 F. 3d at 677; *Pansy*, 23 F.3d at 791.

20. ZHP00458585 (ECF 685, Ex. T): August 2018 customer communications discussing the accuracy of the ZHP Parties' solvent testing and impurity identification procedures for valsartan API. Given ZHP's complete failure to detect the nitrosamine contamination of its valsartan, even after its customer requested an explanation of the resulting unknown peaks in its own chromatographic solvent testing, the public's right to fully understand and assess the failures in ZHP's solvent testing and impurity identification procedures – even if embarrassing to ZHP

– greatly outweighs ZHP's interest in shielding them from the sun's disinfecting rays. *See Avandia*, 924 F. 3d at 677; *Avandia*, 2020 WL 5358287, at *12.

21. ZHP00476678 (ECF 685): May 2015 customer communications regarding ZHP's adoption of the contaminating manufacturing process for its valsartan API. This email chain contains no specific information regarding the process change. Instead, it is a routine business communication between defendants in this case. The Court has already ruled that such communications are not confidential, even under the more liberal standard governing documents that have not been filed with the Court. *Valsartan*, 2021 WL 75258, at *6 (rejecting Torrent's confidentiality designations, and explaining that "[a]t bottom, Torrent's emails involve what appears to be routine business communications"). (*See also* Pls.' Ex. I, J, L, M). Here, under the far more rigorous public right to access standard, the Court similarly rejects such confidentiality designations. *Avandia*, 924 F.3d at 670**.**

22. ZHP02270194 (ECF 685, Ex. U): Early 2017 customer communications regarding sales targets and forecasting data. There is nothing so proprietary that ZHP can establish particularized harm from stripping away the overbroad confidentiality designation. This email chain is nearly four years old, and thus antiquated in this field, and constitutes nothing but a routine business communication between defendants in this case. *See Avandia*, 924 F. 3d at 678. The

Court therefore denies ZHP's motion to keep it under seal. *Valsartan*, 2021 WL 75258, at *6; *see also Avandia*, 924 F.3d at 670**.** (*See also* Pls.' Exs. I, J, L, M).

23. ZHP01893902 (ECF 685, Ex. V): September 2017 customer communications with Novartis, the company that ultimately discovered the nitrosamine contamination in ZHP's valsartan API in 2018. This email does not contain any sales data. Instead, as a routine business communication, it is not subject to sealing in this litigation. *Valsartan*, 2021 WL 75258, at *6; *see also Avandia*, 924 F.3d at 670**.** (*See also* Pls.' Exs. I, J, L, M).

24. ZHP00310874 (ECF 685, Ex. W): Mid-2018 customer communications with Novartis regarding the unknown peaks in its residual solvent testing that it ultimately identified as a nitrosamine. There is nothing proprietary or confidential about the fact that ZHP's valsartan API was contaminated with a nitrosamine – this is at the heart of the very public recall and disclosures about the contamination. Other than that embarrassing fact, this email chain is a routine business communication not subject to seal in this litigation. *Valsartan*, 2021 WL 75258, at *6**.** (*See also* Pls.' Exs. I, J, L, M). To the extent the email chain contains details regarding the contamination of ZHP's valsartan, the public has a right to understand how it occurred, how it was discovered, and how it can be prevented in the future. *Avandia*, 924 F.3d at 670**.** The Court rejects ZHP's attempt to hide that information from the public.

25. ZHP02125655 (ECF 685, Ex. X): This document is substantively similar to item #24, ZHP00310874 (ECF 685, Ex. W), and the Court rejects ZHP's arguments for the same reasons.

26. ZHP01976459 (ECF 685, Ex. Z): December 11, 2017 customer communications regarding a monthly call with Teva. This document does not contain any specifics regarding the topics of the monthly call. It is a routine business communication and therefore not confidential in this litigation. *Valsartan*, 2021 WL 75258, at *6; *see also Avandia*, 924 F.3d at 670**.** (*See also* Pls.' Exs. I, J, L, M).

27. HUAHAI-US00008050 (ECF 685, Ex. AA): Early 2015 customer communications regarding Teva's request to audit at ZHP's Xunqiao site, where ZHP manufactured its contaminated valsartan finished dose. This email chain is a routine business communication. It does not contain any information that would give another company a competitive advantage that would harm ZHP in a specified, narrowly identified way – especially as it is a communication with a customer. *Valsartan*, 2021 WL 75258, at *6; *see also Avandia*, 924 F.3d at 670**.** (*See also* Pls.' Ex. I, J, L, M).

28. ZHP00183600 (ECF 705): A June 2017 audit plan for the ZHP Parties' Chuannan site, where they manufactured their nitrosamine contaminated valsartan API. This document does not contain any proprietary information that could give another company a competitive advantage, nor does ZHP make the type of

particularized showing of harm needed to support its assertion that public dissemination of this routine documentation would be harmful in a particular way. In fact, it is almost entirely blank. ZHP's interest in sealing the document does not outweigh the public's right to access it as a judicial record. *Avandia*, 924 F.3d at 670**.**

29. ZHP00182575 (ECF 705): Late 2017 and early 2018 customer communications regarding ZHP's residual solvent testing of its contaminated valsartan. To the extent this email chain contains any details, those details will not cause ZHP any competitive harm because the testing at issue was inadequate and failed to detect the nitrosamine contamination of ZHP's valsartan – there is certainly no particularized harm established by ZHP. Moreover, the public has a right to access this information in order to assess the cause of the contamination and determine how it can be prevented in the future. *Avandia*, 924 F.3d at 670**.** The Court therefore denies ZHP's motion to seal this document.

12. In an attempt to gloss over the details of the above documents, ZHP's proposed order categorizes them into three categories in an effort to create the false impression that there is something special about these documents: (1) "nonpublic, proprietary technical information, protocols, and processes relating to the research, development, formulation, and manufacture of the ZHP Parties' APIs and drug products, which are presently unavailable to the public," (2) "FDA establishment

inspection reports of the ZHP Parties' manufacturing facilities," and (3) "customer communications." (ECF 859-4 ¶¶ 16, 24, 29). Importantly, the Court may not seal documents in this general manner – ZHP knows this but tries to evade that fundamental principle. *Avandia*, 23 F. 3d at 671 n.5 (quoting *Pansy*, 23 F.3d at 787 n.17).

13. More specifically, with regard to the first category, the public's right to access any of the technical information concerning ZHP's contaminated valsartan greatly outweighs ZHP's interest in shielding its wrongdoing and defective manufacturing processes from the public. *See Avandia*, 924 F. 3d at 677; *Avandia*, 2020 WL 5358287, at *12.[5] With regard to the second category, the Third Circuit

[5] ZHP cites a number of trial court decisions, all but one of which are unpublished, in support of its argument. However, these cases do not actually support ZHP's motion. In *Bock v. Pressler & Pressler, LLP*, No. 2:11-cv-7593, 2014 WL 1233039, at *1 (D.N.J. March 25, 2014), the court denied the movant's motion to seal. Also, the *Bock* court did not apply the more rigorous common law test for sealing judicial records, as explained in *Avandia*, 924 F.3d at 670. *Mars, Inc. v. JCM Am. Corp.*, No. 1:05-cv-3165, 2007 WL 496816, at *1 (D.N.J. 2007), concerned an unopposed motion to seal. In *In re Gabapentin*, 312 F. Supp.2d 653, 669 (D.N.J. 2004), the court denied an investment research company's motion to unseal summary judgment papers filed in pharmaceutical patent holder's infringement suit against prospective manufacturers of generic version. In that case, the investment research company's entire purpose was to uncover information for the competitive benefit of others. Here, ZHP's motion simply attempts to prevent the public from understanding how its drug supply became contaminated with carcinogenic nitrosamines. *Vista India, Inc. v. Raaga, LLC*, No. 07-cv-1262, 2008 WL 834399, at *1 (D.N.J. Mar. 27, 2008), concerned evidence of "cybersquatting" and related claims. This case certainly involves matters of incomparably greater public interest. *Impax Labs., Inc. v. Zydus Pham. (USA) Inc.*, 2:17-cv-13476, 2018 WL 6416910, at *1 (D.N.J. Dec. 6, 2018), and *Valeant Pharm. Luxembourg S.à r.l.*

is clear that "where it is likely that information is accessible under a relevant freedom of information law, a strong presumption exists against granting or maintaining an order of confidentiality whose scope would prevent disclosure of that information pursuant to the relevant freedom of information law." *Pansy*, 23 F.3d at 791. ZHP's admits that these are FDA documents, but it fails to note that they have already been redacted in accordance with the Freedom of Information Act. This Court will not override the public's right to access these documents as judicial records and as records of their own government subject to that act. Third, this Court has already held that routine business communications are not confidential, even under the more liberal standard for unfiled discovery. *Valsartan*, 2021 WL 75258, at *6. Thus, that category of documents cannot possibly be confidential under the more rigorous standard applicable to judicial records. *Avandia*, 924 F.3d at 670.

14. Pursuant to the foregoing Findings of Fact and Conclusions of Law:

It is hereby ORDERED this ___ day of March, 2021 that ZHP's motion to seal the above twenty-nine documents is **DENIED**.

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v. Actavis Labs. UT, Inc., No. 2:16- cv-4344, 2018 WL 1469050, at *3 (D.N.J. March 26, 2016), were both unopposed motions to seal. In *Boehringer Ingelheim Pharma GmbH & Co. KG v. Mylan Pharm. Inc.*, No. 1:14-cv-4727, 2015 WL 4715307, at *1 (D.N.J. Aug. 7, 2015), both parties filed motions to seal their papers, which were not opposed, and Mylan even wrote in support of Boehringer's motion to seal. Similarly, *Depomed, Inc. v. Purdue Pharma L.P.*, No. 13-571, 2017 WL 27460 (D.N.J. Jan. 3, 2017), was an unopposed joint motion. Frankly, these unopposed motions likely do not belong on Westlaw, let alone in a brief in support of a contested motion such as this one.

It is further ORDERED that within seven days of this order, ZHP shall apply the Court's ruling as to these twenty-nine documents to all of its Confidentiality designations, and to the extent similar documents are designated Confidential, the designations shall be removed, and Plaintiffs shall be notified of those de-designations in writing by the end of that seventh day.

s/ Thomas I. Vanaskie
Hon. Thomas I. Vanaskie (Ret.)
Special Master